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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,585	08/10/2005	Hisae Kume	SPO-121	7558

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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,585	KUME ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 August 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/04/07; 04/17/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 17th 2007 has been entered.

Claims 1-24 are examined on their merits, herein, for the applicant's elected specie for milk protein hydrolysate "**whey protein isolate** (WPI)".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 9 and 17 (independent claims, as currently amended) recite the limitation wherein "**the** protein content" is 2.9 to 9 g per 100 ml of the composition, which is ambiguous. It is not clear as to which protein is referred to by such recitation, the protein from "milk protein hydrolysate", the "protein derived from fermented milk", or the total protein content (i.e. the sum of all protein sources in said composition). Appropriate explanation/correction is required.

2. Claims 2, 10 and 18 recite the limitation "**said** milk protein" in one of the instant claims. There is insufficient antecedent basis for this limitation in the claim. The claimed limitation should be appropriately corrected to recite "said milk protein **hydrolysate**" as recited in the broader claim 1, 9 and 17.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-24 (as currently amended) are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al (US 5,714,472, [A]) in view of Kawai et al (1989; [U2)], Davis et al (US 6,998,259 B1, [B]), and Siegenthaler (1983; [U]), taken with Fritsche et al (US 6,737,076 B2; [C]) and Ohashi et al (US 4,499,076; [A2]).

Claims (as currently amended) are generally directed to **a nutritional composition** (suitable for liver disease patients, or patients under high level of invasive stress) comprising a milk protein hydrolysate (elected specie, **whey protein isolate** that may be obtained by enzymatic hydolysis using endoprotease from *Bacillus licheniformis*, and trypsin, ultrafiltration, and HPLC separation as shown in figure 1 of the instant specification) and a protein derived from fermented milk, as proteins; a high oleic acid-containing oil and milk lecithin and/or soy lecithin as lipids; and palatinose (i.e. isomaltulose) as a

carbohydrate; and **a method of providing nutrition** to a patient having liver disease and/or a high level of invasive stress comprising administering said nutritional composition to such a patient (see instant claims 1, 9, and 17, as currently amended).

> *"[E]ven though **product-by-process** claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Gray et al [A] teach an enteral formulation (and a method for providing nutrition using a composition comprising protein, high fat and low carbohydrate; designed for optimized nutrient absorption and wound healing; i.e. for patients under high level of invasive stress) comprising an improved protein source (such as whey protein hydrolysate; see Gray et al, abstract, summary of the invention, column 4; column 5, lines 43-48; examples 2-3, and claims, in particular); a high oleic acid-containing lipid source (as defined in the instant specification on page 14, lines 1-3; such as soy oil; see Gray et al, columns 5-6, in particular) including soy oil and lecithin (see Gray et al, column 5, lines 35-37; examples 1-2, in particular); and carbohydrates (such as maltodextrin and corn starch. It is to be noted that Gray et al recognize the need for optimization of an enteral nutritional composition (suitable for patients under high stress) in order to reduce the risk of over hydration, hyperglycemia, and carbohydrate intolerance, and hence the emphasis on appropriate protein content (a reasonable amount such as about 9 g/100 ml of the formulation; see Gray et al, column 7, formula example No. 3, in particular), high lipid diet (see Gray et al, summary of the invention, column 2, lines 43-55, in particular).

However, a nutritional composition comprising a protein derived from **fermented milk** (as recited in instant claims 3-5 and 11-13); wherein the **palatinose** is used as a

carbohydrate; and wherein the milk protein hydrolysate may be obtained by an enzymatic (using proteases, alcalase and trypsin) hydrolysis of a **whey protein isolate** (**WPI**; see instant claims 6-8 and 14-16), is not explicitly disclosed by the referenced invention of Gray et al.

Siegenthaler [U] discloses the potential nutritive value of cultured dairy products (such as **fresh cheese, quark**, and yogurt; see Siegenthaler, summary, page 252-254, in particular) that are especially suitable for use in children (akin to patients with suboptimal digestive system; in place of fluid reconstituted milk preparations that are linked with lactose-intolerance, or handling-related diarrhea among many populations) as it provides longer shelf-life of the product at ambient temperatures as well as aid in the digestion of residual lactose after ingestion of such fermented milk compositions.

Davis et al [B] teach a milk protein hydrolysate which is obtained by the enzymatic hydrolysis of **WPI** (whey protein isolate such as BiPRO^{TM}; see Davis et al, abstract, summary of the invention, columns 3, 5, 9-10, and claims, in particular) which can be used as a source of antihypertensive peptides (such as having ACE-inhibitory activity) derived from whey proteins (i.e. suitable for use in nutritional compositions for patients under high level of invasive stress).

In addition, Kawai et al provide a disclosure for the usefulness of **palatinose** (or isomaltulose as a source for low-caloric carbohydrate) for patients with conditions such as diabetes, and explicitly suggest its use in a variety of nutritional supplements as a non-calorigenic sweetner (see Kawai et al, page 338, Introduction, i8n particular) that causes no known side effects in patient populations.

Therefore, given the detailed disclosure for the components of a nutritional composition (and its use to provide nutrition to patients under stress and trauma) used in the cited art, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify (i.e. combination and/or substitution of known components) the composition of Gray et al such that it includes a protein from fermented milk such as from fresh cheese, quark (as taught by Siegenthaler); a milk protein hydrolysate which is obtained by enzymatic hydrolysis of a WPI (as explicitly taught by the referenced invention of Davis et al); and a non-calorigenic carbohydrate such as palatinose (as explicitly suggested by Kawai et al).

One of ordinary skill in the art would have been motivated to modify the composition of Gray et al with a reasonable expectation of success using the combined teachings and suggestions of Siegenthaler, Kawai et al, and Davis et al because they explicitly provide suggestions (such as ease of digestibility, anti-hypertensive properties of peptides derived from WPI, and non-calorigenic substitute for carbohydrate source) and method of preparation of such composition (see discussion above) that are suitable for use with patients having compromised digestive system, and/or under high invasive stress conditions, as desired by instant invention.

The claimed limitation of protein content (taken as **total protein content** in the said composition) of 2.9 to 9 g per 100 ml of the composition would have been a matter of routine optimization to an artisan of ordinary skill in the nutritional formulation art (as evidenced by the fact that Gray et al, in fact disclose and exemplify a similar protein amount of about 9 g per 100 ml in their ready-to-use enteral product formulation; see

discussion above). Moreover, **low-protein dietary formulations** have been suggested in past to be used for patients with chronic liver diseases as one of the basic therapeutic tools as disclosed explicitly by Ohashi et al (see column 1, 2nd paragraph, in particular) in order to avoid side effects such as diarrhea, or even renal insufficiency, etc.

Similarly, the claimed limitations of instant claims 7-8 and 15-16 (which is a permeate obtained by further treatment with an ultrafiltration membrane having a molecular weight of 10,000 Daltons, and wherein the chromatogram from reversed phase HPLC separation is shown in Fig. 1.) would have been a matter of routine optimization to a person of ordinary skill in the art at the time this invention was made, as evidenced by the disclosure of Davis et al (and as supported further by the invention of Fritsche et al [C] that discloses the use of alcalase (i.e. an endoprotease from *B. licheniformis)*, trypsin ,and other endoproteases, or combinations thereof to hydrolyse protein sources such as WPI; see column 4, lines 44-65; columns 5-6; example 2-3; and use of ultrafiltration and HPLC separation procedures to obtain the peptides derived from the hydrolysate of WPI) for the preparation of enzymatic hydrolysate of WPI and its use as a component having major health benefits.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made.

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-24 (as currently amended) remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 10/487,237 (from the same inventive entity and same assignee, Meiji Dairies Corp. Tokyo, JP). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-36 in the copending application 10/487,237 are also directed to a composition and methods of using the said composition comprising protein (such as milk proteins), a lipid (such as high oleic acid containing oils, and milk phospholipids), and a carbohydrate (such as palatinose and/or trehalulose). Although, the composition as recited in the copending application 10/487,237 requires certain range of energy percentage supplied from the components (such as proteins, lipids, and carbohydrate), such distribution of the components based on the caloric input would have been a matter of routine optimization

to a person of ordinary skill when using the said composition for a particular patient or subject population depending on the nutritional/caloric requirements.

The two sets of claims are largely coextensive, and thus raise an issue of obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Applicant's Arguments

Applicant's arguments with respect to the pending claims 1-24 (as they pertain to previous prior art rejections of record) have been considered but are moot in view of the new ground(s) of rejections made in this office action.

Pertinent prior art not relied upon in the Rejections

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. FUCHS et al. (US 6,592,863 B2; issued on July 15, 2003), Method to provide nutritional composition; abstract, summary, examples and claims.
2. BUCKE et al. (US 4,587,119; issued on May 6, 1986), Method of reducing dental plaque formation with products for human or animal consumption using isomaltulose sucrose substitute; abstract, columns 5-6.
3. OJIMA et al. (US 7,029,717 B1; issued on April 18, 2006), Sucralose-containing composition and edible products containing the composition, abstract, columns 7-8, in particular.
4. FORSE et al. (US 5,821,217; issued on October 13, 1998) Enteral formulation: low in fat and containing protein hydrolysates (see entire document).

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
Patent Examiner
Art Unit 1657

IRENE MARX
PRIMARY EXAMINER